

## REMARKS/ARGUMENTS

This communication responds to the Final Office Action of January 28, 2010, in which pending claims 1-33 and 35-37 are rejected. A petition and fee for a one month extension of time to reply accompany this Amendment and Response.

Claims 1-33 and 35-37 are pending, with claims 1, 14, 24, 32, and 37 being independent claims. By this Amendment, claims 1, 14, 32, and 37 are currently amended, and no claims have been cancelled or added.

No new matter has been added. Support for the present claim amendments may be found throughout the Specification and Claims as filed, for example at paragraphs [0002], [0008], and [0047].

Applicants have not publicly dedicated, or abandoned, any unclaimed subject matter. Further, Applicants do not acquiesce to any rejections made by the Examiner in the Office action, but have merely amended claims in an effort to expedite prosecution. Applicants reserve the right to pursue prosecution of any presently or previously excluded or cancelled claim embodiments in one or more future continuation and/or divisional applications.

Accordingly, after entry of this Amendment and Response, claims 1-33 and 35-37 are pending. Claims 1, 14, 24, 32, and 37 are independent claims.

### I. Claim Rejections Under 35 U.S.C. §103

#### A. Claims 1-8, 10-18, 20-33, and 35-37 are not anticipated under 35 U.S.C. § 103(a) by Morris et al. (US 6,458,144; hereinafter "Morris") in view of Dore et al. (US 2003/0236473; hereinafter "Dore").

The Examiner rejects claims 1-8, 10-18, 20-33, and 35-37 under 35 U.S.C. § 103(a). The Examiner alleges that "Morris et al. teach a method for manufacturing skeletal implant . . . wherein a donor bone . . . is provided along with evaluating the suitability of the bone and/or dowel for implant use after each step of the manufacturing process is provided." Further, Dore is cited by the Examiner for teaching "high precision modeling of a body part using a 3D imaging system." The Examiner suggests that these teachings make obvious the currently claimed process of evaluating donor bone suitable for implant preparation. Because the independent claims presently recite "non-destructive assess[ment]" of a donor bone to determine parameters

such as bone volume, bone density, mineral density, or size and position of the medullary canal, applicants disagree.

**1. Neither Morris nor Dore teach “non-destructively assessing” donor bone for determining “bone volume, bone density, mineral density, and size and position of a canal,” “morphometric parameters,” or “cortical thickness.”**

According to the M.P.E.P., a proper obviousness rejection based on a rationale of combining prior art elements requires at least a finding that the cited references included each and every aspect claimed “with the only difference between the claim[]” and the cited references “being the lack of actual combination of the elements.” § 2143(A). *See also In re Royka*, 490 F.2d 981, 985 (C.C.P.A. 1974); *CFMT, Inc. v. YieldUp Int’l Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003).

Independent claims 1, 14, 24, 32, and 37 all recite non-destructive assessment of donor bone and measurement of parameters including “cortical thickness,” “morphometric measurements,” and “bone volume, bone density, mineral density, and size and position of a canal.” Neither Morris nor Dore teach these aspects of the present claims.

Morris is incapable of measuring most of these parameters at all, and cannot assess or measure the others without destruction of the bone. Morris simply does not teach measurement of either bone density or mineral density. Additionally, as is evident from Fig. 1A of Morris, the medullary canal is only visible, and thus can only be measured, after the donor bone has been cut. Morris explicitly states that imaging and evaluation occurs “after each step of the manufacturing process.” Without measuring the size and position of the medullary canal, the bone volume cannot be measured. Thus, Morris does not teach these aspects of the current claims.

Dore does not compensate for the failings of Morris. First, Dore, like Morris, is silent as to measurements of “cortical thickness,” “morphometric measurements,” and “bone volume, bone density, mineral density, and size and position of a canal.” This is not surprising as Dore is directed to the fabrication of “metallic, polymeric or ceramic” prostheses, not implants made from donor bone. Dore is silent as to these parameters, because Dore is directed to measurements of the body part surfaces “to create a replica of the body part or an implant tightly fitting the said body part.” Dore, Abstract. Dore is explicit: “[t]his is done by representing the surface (boundaries) of the part of the anatomy under investigation with a global 3D parametric model that can provide a numerical description with arbitrary density [of data] in order to adapt to requirements of different types of N/C fabrication methods.”

Thus, Morris and Dore, together, do not teach each and every aspect of the present independent claims. The Examiner's rejection is inapposite and should be withdrawn.

**2. There is no suggestion or motivation to combine Morris with Dore, because the method of Morris in light of Dore would render the present process unsatisfactory for its intended purpose.**

According to the M.P.E.P., if a "proposed modification would render the [referenced] invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." §2143.01(V), citing to *In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984).

The current claims are directed to non-destructive assessment of donor bone for evaluating donor bone suitability for implantation prior. The presently claimed process "permits accurate planning and preparation of an implant graft that is correlated to the predetermined plan without waste of bone through cutting test specimens to determine the bone parameters." Abstract. The teaching of Morris, wherein donor bone is cut so as to assess parameters such as cortical thickness and size and position of the medullary canal would render the present method unsatisfactory, and is contrary to its intended purpose.

For at least these reasons, the Examiner's rejection is inapposite and should be withdrawn.

**B. Claims 9 and 19 are not obvious under 35 U.S.C. § 103(a) over Morris in view of Dore as applied to claims 1 and 5 above, and further in view of Ateshian et al. (US 6,459,948; hereinafter "Ateshian").**

The Examiner argues that claims 9 and 19 are obvious for the reasons applied above to claims 1 and 5, and because "Morris et al teach . . . wherein the donor bone is cut by an automated device," and "Ateshian et al. teach a method an apparatus for manufacturing prosthesis . . . [by a] numerically controlled fabrication means." Applicants disagree.

According to the M.P.E.P. "if an independent claim is nonobvious under 35 U.S.C. [§] 103, then any claim depending therefrom is nonobvious." § 2143.03, citing to *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Claims 9 and 19 depend from claims 1 and 14, respectively. As detailed above, both claims 1 and 14 are non-obvious over Morris in view of Dore. Because claims 1 and 14 are non-obvious, all claims depending therefrom, such as claims 9 and 19, are also non-obvious.

In addition, neither Morris nor Ateshian describe the presently claimed process "wherein the donor bone is cut by an automated [or computer assisted] device." Morris does not use

"automated," "computer assisted," or "numerically controlled" to describe any aspect of the method of preparing bone implants. Morris is directed to a method of preparing bone implants wherein the implant is visually inspected "after each step of the manufacturing process." This is not automation.

Ateshian also does not describe a process "wherein the donor bone is cut by an automated [or computer assisted] device." On the contrary, rather than cutting a donor bone with an automated or computer assisted device, Ateshian teaches constructing a joint prosthesis by a "means controlled by [a] microprocessor." But the prostheses of Ateshian are not bone, rather the only materials disclosed at Column 5 lines 54-61, are metal and hydroxyapatite. This is not the presently claimed "cutting bone with an automated or [computer assisted] device."

For at least these reasons, the Examiner's rejection is inapposite and should be withdrawn.

### CONCLUSION

This response is being submitted on or before May 28, with the required fee for a one-month extension of time, making this a timely response. It is believed that no additional fees are due in connection with this filing. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.


This application now stands in allowable form and reconsideration and allowance is respectfully requested.

Respectfully submitted,

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